DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
2098 Gaither Road
Rockville, Maryland 20850

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NOV 22 2002

WARNING LETTER

FEDERAL EXPRESS

Mr. Gyo Suk Baek, President and CEO
Choyang Medical Co., Ltd.
451-1, Woebu-Ri
Kunuk-Meon, Kumsan-Kun
Chungnam, Republic of Korea

Dear Mr. Suk Baek:

In reviewing the response received from Mr. Peter Hong to our letter of inquiry dated February 7, 2002, it appears that your establishment is the manufacturer for the Choyang Dana Massager CY5000 (which appears to be a modified physical therapy table with thermal radiators that emit infrared heat, "low frequency" pads for some type of electro-stimulation, and vibration), Choyang JO EUN A CIM (deluxe) (which appears to be a heating pad with a controller and negative potential needles), the Choyang Dana JO EUN A CIM (regular)(which appears to be a heating pad with a controller and negative potential needles), the Choyang Dana CY1000 (muscle stimulator) and the Choyang Dana CY2000 (muscle stimulator).

Under a United States Federal law, the Federal Food, Drug, and Cosmetic Act (the Act), these products are considered medical devices because they are intended for use in the diagnosis or treatment of a medical condition or intended to affect the structure or function of the body, 21 U.S.C. 321(h). The law requires that manufacturers of medical devices obtain marketing clearance for their products from FDA before they may offer them for sale. This helps to protect the public health by ensuring that new medical devices are shown to be either safe and effective or substantially equivalent to other devices already legally marketed in this country.

Our records do not show that there is marketing clearance or approval in effect for the Choyang Dana Massager CY5000, the Choyang Dana CY2000, the Choyang Dana CY1000, the Choyang Dana JO EUN A CIM (deluxe), and the Choyang Dana EUN A CIM (regular) devices that you are offering for sale in this country. The kind of information you need to submit in order to obtain this clearance is described in FDA regulations at Title 21 Code of Federal Regulations, Part 807. You may also find the requirements at www.fda.gov/cdrh/devadvice/3122.html. After you submit this information, FDA will evaluate it and decide whether your devices may be legally marketed in this country.

Because your products do not have marketing clearance or approval from FDA, they are in violation of the law. In legal terms, your products are adulterated under Section 501(f)(1)(B) and misbranded under section 502(o) of the Act. These products are adulterated under the Act because you did not obtain pre-market clearance based on information developed by you that shows your devices are safe and effective. These products are misbranded under

the Act because you did not submit information that shows that your devices are substantially equivalent to other devices that are legally marketed.

A review of our records also revealed that your firm has not registered for the year 2002, has not properly listed all of its products, and has not identified a U.S. agent, as required by FDA regulations at 21CFR 807.40. Any establishment within any foreign country that is engaged in the manufacture or processing of a device that is imported or offered for import into the United States must register and list such device in conformance with 21 CFR Part 807, subpart B. Each establishment must also submit the name, address, and phone number of its United States agent as part of its initial and updated registration information. The U.S. agent must reside or maintain a place of business in the United States. The failure to comply with these requirements causes your devices to be misbranded within the meaning of sections 502(o) and 502(t)(2) of the Act. With narrow exceptions not relevant here, no device may be imported or offered for import into the United States unless it is the subject of a device listing and is manufactured or processed at a registered foreign establishment.

Given the serious nature of these violations of the Act, your device may be detained without physical examination upon entry into the United States until these violations are corrected.

Please notify this office in writing of the steps you are taking to correct the noted violations. We also ask that you explain how you plan to prevent this from happening again. If the documentation is not in English, please provide an English translation to facilitate our review. Please address your response to:

Christy Foreman, Chief
Orthopedic, Physical Medicine & Anesthesiology Devices Branch
Division of Enforcement B, Office of Compliance
Center for Devices and Radiological Health
Food and Drug Administration
2098 Gaither Road
Rockville, MD 20850

If you have any questions, please contact Brenda Hayden at (301) 594-4659.

Sincerely yours,

Christy Foreman for

Philip J. Frappaolo
Acting Director
Office of Compliance
Center for Devices and
Radiological Health